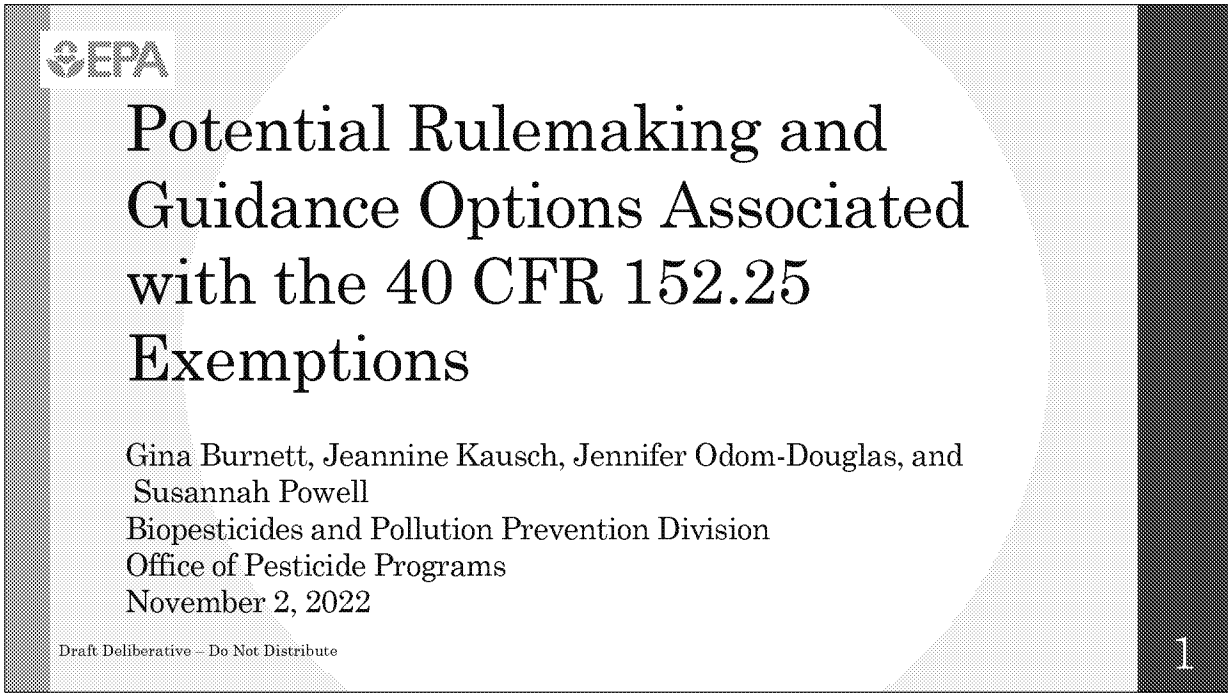
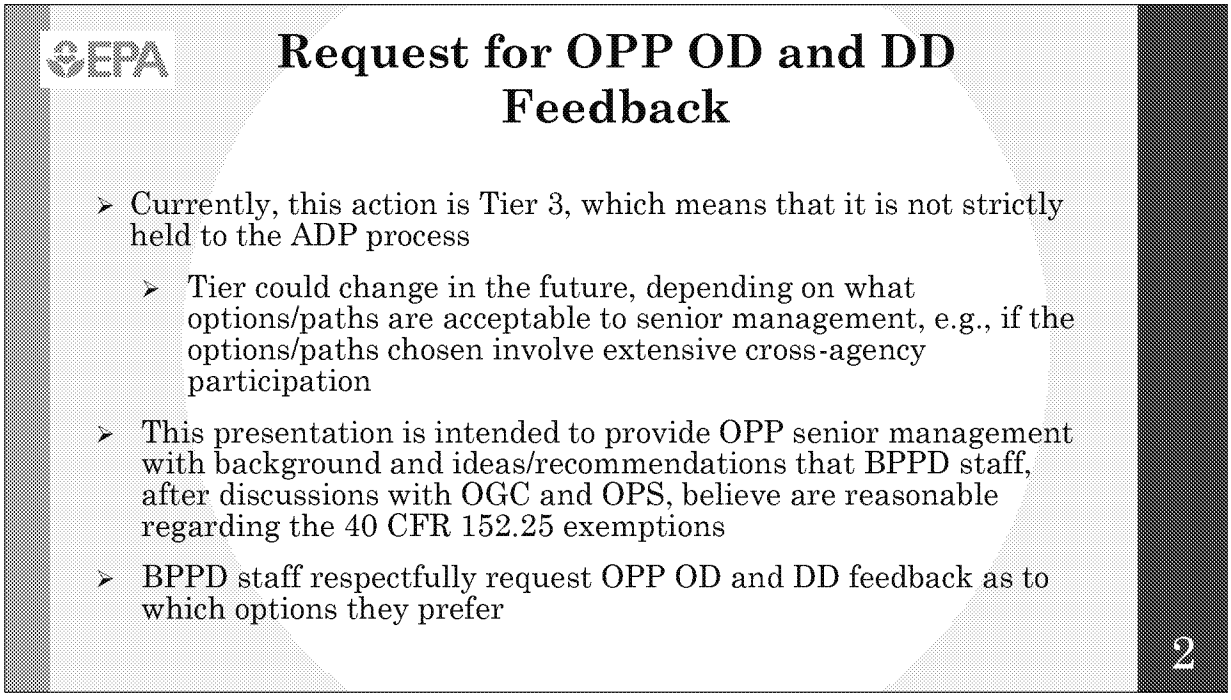


Good afternoon and welcome to the continuation of BPPD's presentation on potential rulemaking and guidance associated with the 40 CFR 152.25 exemptions. Given that background on the exemptions, issues with the exemptions, and comments received on the 2021 ANPR were covered with the first briefing at the end of July, we are intending to jump right into the issues and recommended options to address them. If you would like to look back at what was covered previously, we have left the first 10 slides covering that material in this slide deck. Alternatively, they can be found in the slide deck distributed for the first briefing, which can be found in the invitation from the previous meeting or in the chat.



Just to make clear what this presentation is . . . It is intended to provide you with background and ideas/recommendations on ways we could address some of the current challenges/issues encountered by various stakeholders (i.e., EPA, states, consumers, and industry) regarding some of the exemptions under 40 CFR 152.25. I emphasize the use of "some" in my previous statement because it would likely be difficult to solve all the issues with all the exemptions, but we believe there are items that can be tackled to make these regulations better for all stakeholders involved. After these briefings, we would respectfully request your feedback on what options you prefer. Please note that this action is a Tier 3 action currently; hence, it is not strictly held to the ADP process. That may change in the future, but we'll cross that bridge when we get to it.

Overview

washingtonpost.com

- Background
  - FIFRA Exemption History
  - Minimum Risk Pesticide Exemption
  - Issues/Challenges
  - Resultant Advanced Notice of Proposed Rulemaking
- Public Comments
- Potential Rulemaking and Guidance Options
- Timeline

3

In several places in the slides, you will notice that text is underlined. When you see this, a hyperlink to supporting material/information is often provided. We will be focusing on the last two points, emphasized in red, on this slide in this particular briefing.

Background – FIFRA Exemption History

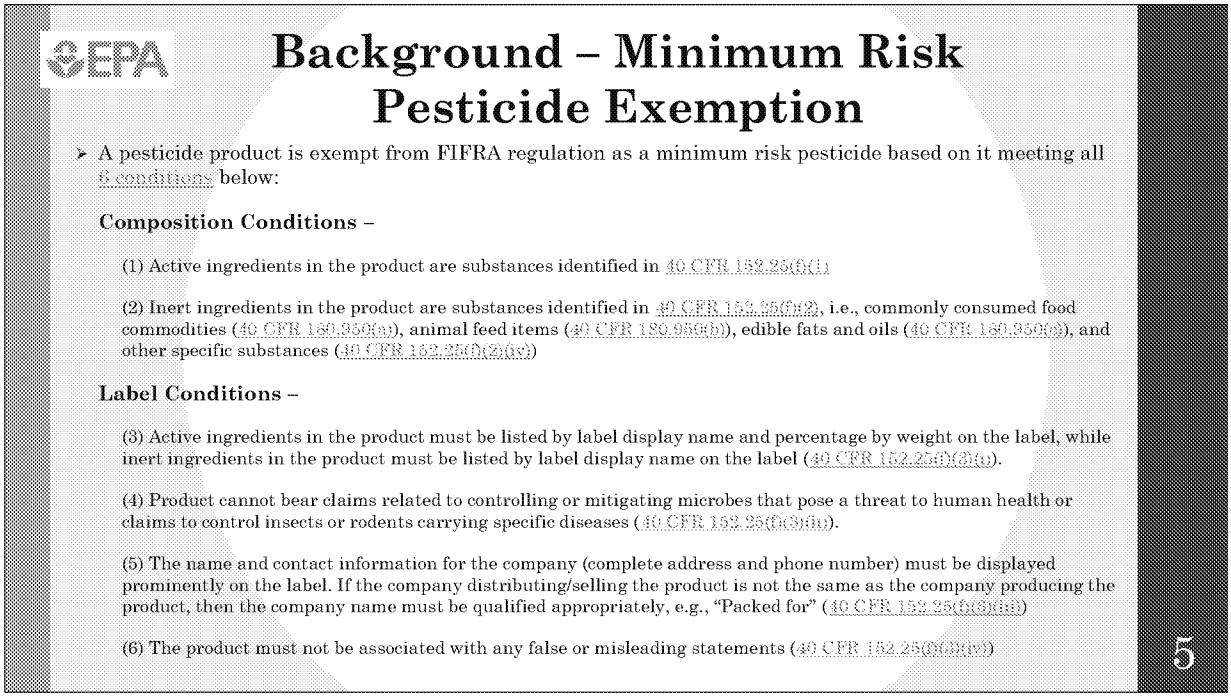
- FIFRA section 25(b) gives EPA the authority to exempt from the requirements of FIFRA by regulation any pesticide that is "of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA]"
- Using the authority above, EPA established exemptions from FIFRA regulation for certain pesticides in 40 CFR 152.25:
  - 1988 – Treated articles or substances; pheromones and pheromone traps; preservatives for biological specimens; foods; and vitamin hormone products
  - 1994 – Natural cedar
  - 1996 – Products that consist of ingredients that EPA determined pose minimum risk to humans and the environment (aka "minimum risk pesticides")
- Vitamin hormone products were moved to 40 CFR 152.6 ("exclusions from FIFRA regulation") in 2001, and this resulted in some exemptions being redesignated within 40 CFR 152.25, e.g., minimum risk pesticides ended up under 40 CFR 152.25(f)
- Minimum risk pesticide exemption last updated in 2015

There are other exemptions in 40 CFR (in 40 CFR 152.20 ("pesticides adequately regulated by another Federal agency") and 40 CFR 152.30 ("pesticides that may be transferred, sold, or distributed without registration"), but this presentation will focus on those under 40 CFR 152.25.

With the 2015 minimum risk pesticide exemption rulemaking, the following items were done:

Inert ingredient list codified instead of it being located only on EPA's website (https://www.epa.gov/sites/default/files/2021-03/documents/minrisk_inert_ingredients_w_tolerances_2016-11-16.pdf)
Chemical identifiers added to active and inert ingredients in the regulations if applicable, i.e., CAS Reg. Nos. (https://www.cas.org/about/faqs)
Ingredients need to be listed on the product label with a specific label display name
Company name and contact information needs to be prominently displayed on the product label

Changes intended to make it easier for manufacturers, the public, and inspectors to determine the specific chemical substances that are permitted in minimum risk pesticide products and to provide more consistent information for consumers. Even with these latest improvements, some issues have been ongoing and remain with this exemption.

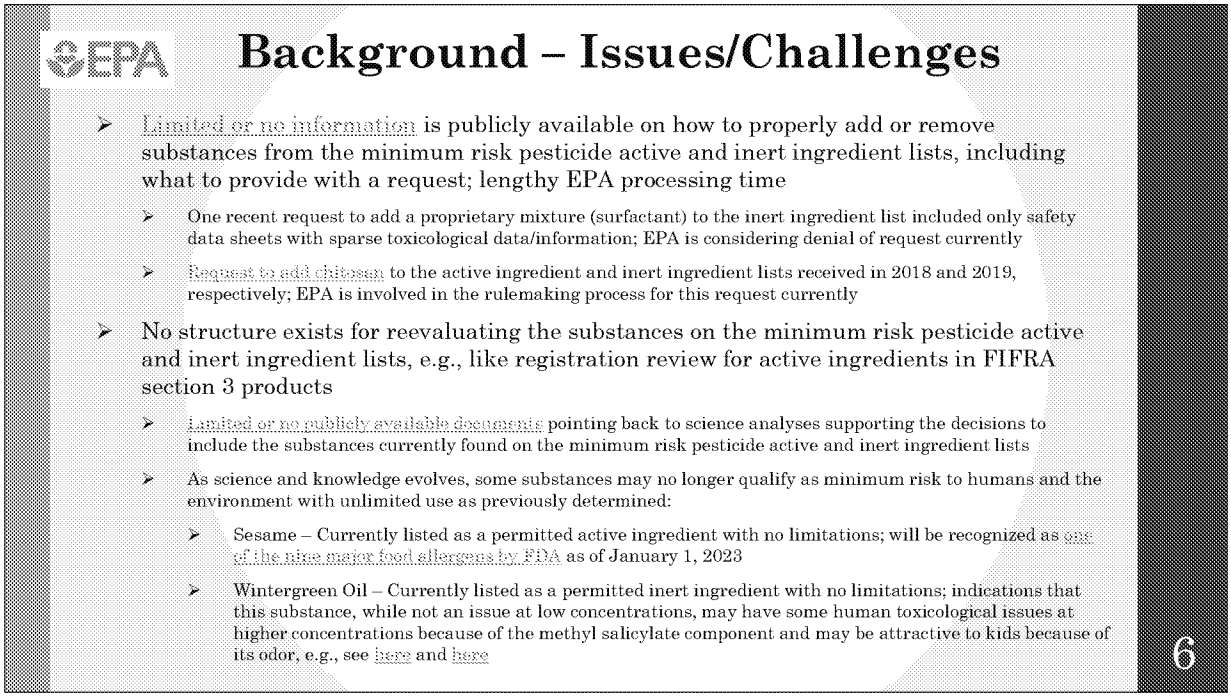


Condition #2 – More information on how EPA views the meaning of "commonly consumed food commodities," "animal feed items," and "edible fats and oils" can be found on EPA's website (https://www.epa.gov/minimum-risk-pesticides/commonly-consumed-food-commodities)

Condition #3 – A label display name is a name for an ingredient that may be more readily recognizable to the general public than a chemical name, e.g., "eugenol" is the label display name for the chemical 4-Allyl-2-methoxyphenol.

With the update in 2015, the label display name for active and inert ingredients was added to the regulations and required to appear on minimum risk pesticide labels. This was done mainly to help inspectors efficiently determine whether a product follows the exemption and to provide improved clarity and transparency for consumers who want more information about the ingredients used in a product.

Condition #4 – Please note the distinction between microbes that are public health pests (claims not allowed) and insects and rodents that are public health pests (claims allowed but only if the pests are not connected to diseases they may transmit). Also, some public health pests (e.g., certain birds like rock doves) are not covered by this condition. Finally, it may be unclear whether certain public health pests are covered by this condition. For example, even though the condition names "ticks that carry Lyme disease" as being covered, the words prior to that speak to "insects and rodents" specifically, and ticks are not insects (they are arachnids).



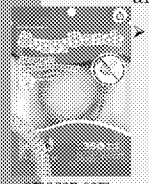
The issues/challenges raised in this slide and the slide that immediately follows impact several different stakeholders (i.e., EPA, states, industry, and consumers) depending on the issue/challenge.

Another potential problematic ingredient (re: limited or no supporting scientific analysis) to discuss if there is time:

Cottonseed Meal – This substance is currently listed as a permitted inert ingredient with no limitations. There are indications that gossypol concentrations, which is a toxic compound produced in cotton plants to protect from insect damage, in this substance may be variable based on several factors, e.g., extraction method used. Gossypol may promote clinical poisoning, liver damage, male and female reproductive toxicity, and immunological impairment in certain animals (monogastric animals like rodents and fish) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4033412/).

Background – Issues/Challenges

- Many states still require registration of products that EPA considers to be exempt. States find issues with these products and routinely question if things comply with the exemptions, particularly the minimum risk pesticide exemption. This places burden on EPA to continually answer these questions through ECRs, through ombudspeople, and in other ways. For the minimum risk pesticide exemption, some topics that often come up and that EPA has not generally been able to provide clear answers on are as follows:



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- **Claims**
  - Likely exaggerated efficacy of public health pesticide products, e.g., claims that wristbands containing certain minimum risk active ingredients repel mosquitoes for many hours of wear (e.g., up to 350 hours) and are effective a certain distance away from the individuals wearing the wristband (e.g., up to 4 feet)
  - Some information on EPA's website about this aspect of the exemption, but nothing that covers claims like the above specifically; would likely need data generation on the product to support an assertion that the product does not work as described and that the claim is false and misleading
- **Composition**
  - Inert ingredients acting as active ingredients and vice versa
  - 2005 – Supposed minimum risk pesticide product used against rodents with corn oil as the active ingredient and corn cob and molasses as the inert ingredients; sent letter to company saying the product needed to be registered because corn cob was believed to be the active ingredient
  - 2011 – Supposed minimum risk pesticide products used against insects with wintergreen oil as an inert ingredient; drafted over 30 ECRs that were hundreds of pages long with references to the company's patents, registration history with EPA, and advertising materials. Case never moved forward and questions from the states about the products, as well as others like these, have continued
  - 2020 – A workgroup of the Association of American Pesticide Control Officials put together guidance for state regulators on this issue, given its prevalence when states evaluate minimum risk pesticides and whether they qualify for the exemption

pestcontrol.com

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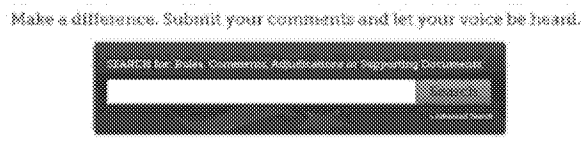
Regarding the bullets under "Claims" in this slide, these are in relation to a question recently received from a member of the public (although we have received similar questions in the past). The individual asking the question had concern that a summer camp that she was sending her kids to was recommending that she buy the "BuggyBands" product (see picture) to protect her kids from mosquitoes. She explained that she spends a lot of time outdoors with her husband, and they use DEET for protection against mosquitoes. In doing some additional research, she further explained that DEET appears to have efficacy for 8-10 hours before needing reapplication. Given that the BuggyBands product claims to have 350 hours of efficacy, does not contain DEET, and is not registered/reviewed by EPA, she concluded that it appears that the "350 hour" claim is false and misleading. This is an excerpt from her email: "These products should not be sold online as they are lying and misleading to consumers and kids are being put in real danger from mosquito bites for not being adequately protected as wearing them for extended periods of time has zero repellent properties." In addition to pointing out her concern, she asked who could be contacted to look into these products further to potentially bring enforcement for unsubstantiated, misleading claims . . . EPA, CDC, BBB, FTC, etc.???

Regarding the 2nd bullet under "Composition" in this slide, the letter explains that EPA was able to determine that the corn oil was not the active ingredient in the product because it is used in challenge diet administered to rodents, at 1000X the concentration in the product, in laboratory efficacy studies.

Regarding the 3rd bullet under "Composition" in this slide, wintergreen oil and other essential oils may work against insects via the octopamine receptor; octopamine regulates an insect's heart rate, movement and metabolism. Please see https://pestzone.net/eco-friendly-services/eco-friendly-mosquito-control/ and https://academic.oup.com/jee/article/109/6/2388/2404590?login=true for additional information.

Background – Resultant ANPR

- Advanced Notice of Proposed Rulemaking published on April 8, 2021. Sought feedback on:
  - The petition process for adding/removing active or inert ingredients to/from the respective ingredient lists for minimum risk pesticides (40 CFR 152.25(f))
  - How active and inert ingredients are evaluated by EPA for inclusion on or removal from the respective ingredient lists for minimum risk pesticides (40 CFR 152.25(f))
  - Whether consideration should be given to amending existing exemptions or adding new classes of pesticidal substances for exemption



nrcs.usda.gov

Public Comments Received

- 40 comments received from AAPCO, states, other federal entities, industry, environmental groups, and individuals
- Main theme throughout the comments was support for effort by EPA to provide more clarity/information/guidance/oversight regarding exemptions
- Comments suggested that EPA consider the following:
  - Exempt certain PIPs (e.g., those used for conservation purposes like American chestnut engineered to be resistant to chestnut blight) and antimicrobial copper alloy products
  - Ensure the exemption petition process has a defined timeframe and applies to all exemption situations
  - 40 CFR 152.25(a) ("treated articles or substances") – Retain EPA's current extension of the treated article exemption to pesticide-treated seed, as it is consistent with FIFRA authority and eliminates duplicative registration
  - 40 CFR 152.25(b) ("pheromones and pheromone traps") – Revise to include all semiochemicals (e.g., allelochemicals that are used for interspecies communication like juglone, which is released by black walnut and inhibits the growth of other plants = less competition for resources) and other technologies besides traps (e.g., semiochemical-containing glue)
  - 40 CFR 152.25(d) ("foods") – Revise to include a definition of "food" and modification to other pest behavior besides just "attracting" (e.g., repelling)

Public Comments Received

- Comments suggested that EPA consider the following (continued):
  - 40 CFR 152.25(f) ("minimum risk pesticides") –
    - Exclude public health pest products from qualifying for this exemption or require data to support these products
    - Register/do not register products under a reduced-risk scheme
    - Ensure there is a better enforcement framework
    - Deal with state inconsistencies by providing better guidance on the conditions
    - Require additional labeling (e.g., Keep Out of Reach of Children and human hazard precautionary statements)
    - Provide better guidance or limitations on dual-use ingredients, i.e., those substances that can be used as both active and inert ingredients
    - Remove requirement to list inert ingredients on the product label
    - Incorporate the petition process into the CFR and move the ingredient lists out of the CFR
    - Add to the active and inert ingredient lists, e.g., USDA provided several tables of substances it believes should be added to the lists
    - Change or add to the criteria to be used by EPA to determine whether a substance can be added/removed to the lists
    - Require adverse effects reporting
    - Add more conditions to the exemption, e.g., mandate generation of data in support of efficacy claims for public health pests
- Will not be able to respond to all comments as they are wide ranging; intend to focus on the process for petitioning EPA for an exemption, the criteria used by EPA to evaluate substances for addition to/removal from the minimum risk pesticide ingredient lists, setting up a one-time reevaluation process for looking at substances already on the minimum risk pesticide ingredient lists, modifying two exemptions, and creating another exemption

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